

adherence/persistence and eight were able to improve the blood glucose levels of patients (double counting in three cases); five had no effect at all. Four dimensions of the methodological quality of AI programs were identified: 1) measurement of adherence/persistence/clinical outcomes, 2) measurement of NA/NP causes, 3) use of effective/validated intervention measures; and 4) effective program evaluation. The authors defined 5 detailed methodological requirements per dimension and, based on this, developed a corresponding scoring model (MIN Score 0, MAX score 20). All 19 AI programs were evaluated in the scoring model (average score 8.05): • Score <5: 3 AI—no adherence/blood glucose level improvement; • Score 5–9: 8 AI—6 with improvement in both adherence and/or blood glucose levels; • Score >9: 8 AI—all improved adherence and/or blood glucose levels. **CONCLUSIONS:** The scoring model provides a starting point for the methodical evaluation of AI. However, further development and testing of both the elements and construction is needed for medical indications other than diabetes type II.

PDB66

THE 8-ITEM MORISKY MEDICATION ADHERENCE SCALE MMAS: TRANSLATION AND VALIDATION STUDY OF THE MALAYSIAN VERSION

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OBJECTIVES: To translate the MMAS into the Malaysian language, and to examine the psychometric properties of the Malaysian version of the MMAS among patients with type 2 diabetes, including its validity and reliability. **METHODS:** After obtaining permission, a standard “forward-backward” translation procedure was used to create the Malaysian version of the MMAS from the original English version. A convenience sample of 223 outpatients with type 2 diabetes was identified between May and September, 2009. All data were collected from the Penang General Hospital, Penang, Malaysia. Instruments consisted of the Malaysian version of MMAS, the Malaysian version of the old four-item Morisky scale and a sociodemographic questionnaire. Medical records were reviewed for hemoglobin A1C (HbA1C) levels and other clinical data. Reliability was tested for internal consistency using Cronbach's α coefficient. Validity was confirmed using convergent and known group validity. **RESULTS:** Employing the recommended scoring method, the mean \pm SD of MMAS scores was 6.13 \pm 1.72. Moderate internal consistency was found, (Cronbach's α = 0.675), the test-retest reliability value by using Spearman's rank correlation was 0.816 (P < 0.001), a positive correlation between the eight- and four-item MMAS was found (r = 0.792; P < 0.01). For known group validity, a significant relationship between MMAS categories and HbA1c categories (χ^2 = 20.261; P \geq 0.001) was found. The MMAS sensitivity and specificity, with positive and negative predictive values were 77.61%, 45.37%, 46.84% and 76.56%, respectively. **CONCLUSIONS:** The MMAS can be used for medication adherence measurement in diabetes. The findings of this validation study indicate that the Malaysian version of the MMAS is a reliable and valid measure of medication adherence which can now be used in clinical practice.

PDB67

FACTORS INFLUENCING VALUATION OF- AND WILLINGNESS TO PARTICIPATE IN- A LIFESTYLE INTERVENTION: AN EXPLORATORY CONJOINT ANALYSIS WITH DIABETES TYPE 2 PATIENTS

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OBJECTIVES: The last decade several studies have proven that lifestyle interventions can be effective for people with or at risk for diabetes. Because effectiveness of preventive interventions is affected by non-participation (adherence), it is important to understand factors influencing people's willingness to participate in a lifestyle intervention. Therefore, the aim of this exploratory analysis is to examine which factors of a lifestyle program influence its valuation and willingness to participate. **METHODS:** We used conjoint analysis to empirically examine associations between the factors that influence participation and participants' valuation of an intervention and participants' willingness to participate in a lifestyle intervention. For this purpose participants received a questionnaire with four hypothetical lifestyle interventions. They were asked to value the hypothetical scenarios with a grade from “1” to “10” and furthermore they were asked if they would be willing to participate in these hypothetical programs. Linear and logistic regression techniques were used for the analyses. **RESULTS:** The factors “group activity,” “counselling,” and “receiving money” were positively associated with the scores of the valuation of the programmes. Logistic regression analysis showed that money was the only factor that was independently associated with respondents' willingness to participate in a lifestyle intervention. Subgroup analysis showed that receiving an amount of money was not associated with willingness to participate, but having to pay is negatively associated with participation in the lifestyle intervention. **CONCLUSIONS:** It appeared that only financial disincentives were independently associated with willingness to participate in a lifestyle intervention. Our conjoint analysis results suggest that financial incentives, in the form of bonuses, cannot be used to encourage people to participate in lifestyle interventions. Financial incentives, in the form of payments might however discourage participation, regardless of the content of the program.

PDB68

HEALTH RELATED QUALITY OF LIFE (HRQL) AND EQ-5D UTILITIES IN A TYPE 2 DIABETES (T2D) POPULATION: RESULTS FROM A SWEDISH SURVEY

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OBJECTIVES: To present HRQL data from a previously presented survey on T2D patients' perceived quality of care in Stockholm, Sweden. **METHODS:** A postal survey including EQ-5D was distributed to 1000 members of the Stockholm Diabetic Patient Association and 1000 patients from five primary health care centers. Patients were randomly selected, >18 years, having a diabetes diagnosis. Analysis of variance was used to test the statistical hypothesis that patients within each subgroup had equal mean utility. **RESULTS:** Response rate was 65% (1319/2000 questionnaires). T2D diagnose was reported for 961 respondents of which 858 completed the EQ-5D questionnaire. Mean age 69 years, 48.5 % female, BMI 28.4 kg/m², mean duration of T2D 11.3 years. Overall, the mean (SD) utility was 0.765 (0.260) and the current health status reported on the VAS scale was 0.727 (0.189). Patients without any hypoglycemic episode the previous month had a utility of 0.799 while those with 1, 2–5 or >5 episodes reported 0.774, 0.687 and 0.633, respectively. More than one hypoglycemic episode resulted in significantly lower utility compared to none or only one episode (P < 0.0001). The utility of obese patients, 0.704, was significantly lower than for patients of normal weight, 0.806, or overweight, 0.790 (P < 0.0001). The utility of patients not considering themselves responsible for the management of their T2D was significantly lower, 0.608, compared to patients taking a limited, 0.774, or full, 0.759, responsibility (P = 0.0005). Patients considering themselves having insufficient knowledge to cope with their T2D reported a lower utility, 0.689, compared to patients with sufficient knowledge, 0.789 (P < 0.0001). Male respondents had a higher utility, 0.796, compared to females, 0.731 (P = 0.0002). **CONCLUSIONS:** Experience of hypoglycemic episodes, obesity, gender, patients' perception of personal responsibility and perceived knowledge about type 2 diabetes has significant impact on health related quality of life in patients with type 2 diabetes.

PDB69

UTILITY VALUES FOR DIABETES COMPLICATIONS

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OBJECTIVES: Cost-utility analysis in diabetes requires utility estimates for diabetic complications. Models frequently rely on UKPDS data. UK requirements for preference elicitation have changed since UKPDS publication. We conducted a systematic review of the literature to identify utility values for diabetes complications suitable for use in Health Technology Assessment (HTA). **METHODS:** A systematic search of online databases was conducted using key words relating to diabetes, major complications, utility assessment and quality of life. Reference lists of identified citations were reviewed. Studies reporting utility single-index measures in patients with any of 33 pre-specified diabetes related states were included: states considered were diabetic complications and adverse events associated with anti-diabetic therapies (AETs). Papers were qualitatively assessed: criteria included relevance of studied population to Type 1 or Type 2 diabetes, sample size, methodological quality and consistency with current UK HTA guidelines. Comorbidity is common in diabetes: methodology papers addressing combination of utility values were identified in a structured search and reviewed. **RESULTS:** The search returned 3024 hits, 169 articles were reviewed and 32 publications were identified as suitable for review. Utility or disutility values suitable for UK HTA were obtained for 23 diabetes states. For 10 complications, including late stage renal disease and some AETs, no utility value were identified that met UK HTA criteria. There is no consensus in the literature on how utility measures should be combined in patients with more than one complication. **CONCLUSIONS:** We identified a set of utility values suitable for economic analysis for HTA in diabetes. To further inform UK HTA, additional research should create robust utility values for diabetic renal disease, and evaluate the empirical accuracy of alternative methods of combining utility values in patients with multiple complications.

PDB70

MEASUREMENT OF HRQOL USING EQ-5D IN TYPE 2 DIABETES MELLITUS PATIENTS TREATED WITH ORAL ANTI-DIABETIC DRUGS IN CHINA

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OBJECTIVES: The study is to measure the health-related quality of life (HRQOL) in type 2 diabetes mellitus (T2DM) patients with oral anti-diabetic drugs (OADs) therapy using the Chinese version of EQ-5D, and examine their health status. **METHODS:** The study was a cross-sectional survey conducted at 75 hospitals in nine cities in China. There were 9577 T2DM patients administered with OADs therapy completed the questionnaires. The survey period was from December 3rd, 2008 to July 31st, 2009. Patients evaluated their health status using five dimensions (5D) and a visual analog scale (VAS). Descriptive statistics was used to describe patients' demographic characteristics, duration of the disease, the frequency of 5D responses and VAS score. STATA 9.2 was used for the analyses. **RESULTS:** The mean age of patients (\pm SD) was 59.5 \pm 12.7 years. 51.1% were male. The mean body mass index (\pm SD) was 24.3 \pm 3.4 kg/m². The mean duration of disease (\pm SD) was 7.9 \pm 6.3 years. For the five dimensions

of EQ-5D, the frequency of T2DM patients responding as having "some problem" and "extreme problem" was 4.6% and 1.6% for mobility, 7.9% and 1.4% for self-care, 13.9% and 1.7% for usual activities, 27.5% and 1.1% for pain/discomfort, and 26.6% and 1.3% for anxiety/depression, respectively. The mean VAS score (\pm SD) of patients was 70.4 ± 15.1 . **CONCLUSIONS:** The rates of T2DM patients with "some problem" in pain/discomfort, and anxiety/depression were relatively high; rate with "extreme problem" for usual activities was also higher than other dimensions. The results of 5D were consistent with the low VAS score. These findings imply that there was a significant impact on the health status of T2DM patients with OADs therapy due to pain/discomfort, and anxiety/depression. It underscores the urgent need to adopt effective measures toward prevention and control of diabetes to improve patients' quality of life.

PDB71

QUALITY-ADJUSTED LIFE-YEAR (QALY) WEIGHTS ASSOCIATED WITH DIFFERENT SEVERITY LEVELS OF DIABETIC RETINOPATHY

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OBJECTIVES: The objective of this study was to elicit quality-adjusted life-year (QALY) weights for the different severity levels of diabetic retinopathy (DR) and to evaluate the adequacy of using certain health-related quality of life (HRQoL) instruments for this purpose. **METHODS:** The study population comprises 151 patients with diabetes (type 1 and 2) that either attended the eye clinic at Linköping University Hospital or were registered at any of the two vision centrals in Östergötland County, Sweden. Participants were interviewed over the phone using time trade-off (TTO) questions, the EuroQol Health Questionnaire (EQ-5D), the Health Utilities Index Mark III (HUI-3) and the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25). The effect of other variables than DR on QALY weights was investigated using ANCOVA and the generic instruments were tested for correlation with NEI-VFQ-25. **RESULTS:** The ranges of the QALY weights estimated with the three generic instruments were for no DR, BR, PDR, maculopathy and legal blindness 0.81–0.88, 0.72–0.78, 0.75–0.82, 0.74–0.81 and 0.39–0.68 respectively. In general, the differences in QALY weights between the different severity levels were reduced when adjusted for clinical characteristics and co-morbidities. The difference in QALY weights between the patients with no DR and legal blindness was significant for all instruments. The correlations between the results from NEI-VFQ-25 and TTO, EQ-5D score, EQ-5D VAS and HUI-3 were 0.27, 0.31, 0.38 and 0.68 respectively. **CONCLUSIONS:** This study presents QALY weights for different severity levels of DR, which can be used in cost-effectiveness analyses of interventions directed to DR. Of the instruments we used, HUI-3 seems to be the most sensitive to changes in HRQoL due to progression of DR.

PDB72

FURTHER DEVELOPMENTS OF THE QUALITY OF LIFE ASSESSMENT OF GROWTH HORMONE DEFICIENCY IN ADULTS (QOL-AGHDA)

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OBJECTIVES: The QoL-AGHDA is the first true quality of life (QoL) measure for adult growth hormone deficiency and is widely used in clinical practice and trials. In the UK NICE advises that scores on the QoL-AGHDA should be used to guide treatment selection. The scale has good psychometric properties and has been shown to be responsive to changes in disease severity. The objective of the study was to adapt the QoL-AGHDA for the Czech Republic, Poland, Serbia, Slovakia and Brazil. **METHODS:** The adaptation in each country required three stages: Translation, cognitive debriefing and a validation survey. The dual panel translation method was used to ensure the items were translated accurately and expressed in everyday language. Cognitive-debriefing interviews with local patients assessed face and content validity. The validation survey tested the psychometric properties of the new scales and included the Nottingham Health Profile (NHP) as a comparator measure. **RESULTS:** Validation data are not available for Slovakia. Mean scores on the new versions of the QoL-AGHDA ranged from 6.2 to 11.8 (maximum possible = 25). Internal consistency ranged from 0.89–0.91 and test-retest reliability from 0.88–0.93. QoL-AGHDA scores were statistically significantly related to; perceived general health and level of fatigue in the Czech Republic, perceived physical activity and level of fatigue in Poland and Serbia and to perceived general health and rated QoL in Brazil. Across the countries mean correlations with NHP sections were (as expected) highest with energy level and emotional reactions (correlations 0.68–0.83) and lowest with sleep disturbance and pain (correlations 0.38–0.46). **CONCLUSIONS:** This study indicates that (with the exception of Slovakia which requires further validation) the new language versions of the QoL-AGHDA meet the standards of the original UK version and the other 9 existing versions. The new adaptations represent valid and reliable tools for measuring QoL in international clinical trials.

THE PANORAMA PAN-EUROPEAN SURVEY: HYPOGLYCAEMIA ASSOCIATED WITH DIFFERENT PHARMACOLOGICAL TREATMENTS FOR TYPE 2 DIABETES

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OBJECTIVES: Hypoglycaemia can be a side effect of glucose-lowering treatment in patients with type 2 diabetes (T2D) that may counterbalance the beneficial effects of diabetes control. PANORAMA is a large (n = 5156) pan-European cross-sectional survey (NCT00916513) of patients assessing patient reported outcomes and glycaemic control. This subgroup analysis compared rates of severe and non-severe hypoglycaemic events in patients taking different pharmacological treatment regimens. **METHODS:** Patients with T2D were randomly or consecutively selected from medical practices in eight countries. Patients were aged ≥ 40 years, with T2D diagnosed >1 year and a clinic medical record available >1 year. All patients received dietary/exercise advice and most were also taking either oral antidiabetic drugs (OADs) and/or injectables (insulin and/or GLP-1 receptor agonists). Patients included in this subgroup analysis had been taking the same pharmacological treatment regimen for ≥ 12 months. Patient-reported frequency of severe (symptomatic episodes requiring external assistance) and non-severe hypoglycaemic episodes in the past year were examined. **RESULTS:** In this subgroup analysis 3106 patients were evaluated including: 1346 taking only OADs without secretagogues; 1452 taking only OADs including secretagogues (sulphonylurea/glinides) and 308 on insulin alone. The percentages of patients experiencing >1 non-severe hypoglycaemic episode in each treatment group were: 8.9% for patients taking OADs without secretagogues; 17.5% for patients taking OADs including secretagogues and 47.4% for patients using insulin alone. The differences between these three treatment categories (pair-wise comparisons) were highly significant ($P < 0.001$). The percentage of patients reporting ≥ 1 severe hypoglycaemic episode was greater for OADs including secretagogues versus no secretagogues (3.0% versus 1.3%; $P = 0.011$) and for insulin alone versus OADs including secretagogues (13.7% versus 3.0%; $P < 0.001$). **CONCLUSIONS:** Among patients with T2D on glucose-lowering medication, rates of non-severe and severe hypoglycaemic episodes were lowest amongst patients treated with OADs not including secretagogues and highest among patients treated with insulin alone.

PDB74

TYPE 2 DIABETES PATIENT PERSPECTIVES ON HYPOGLYCAEMIA

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OBJECTIVES: Understanding the perspectives of Type 2 Diabetes (T2D) patients on hypoglycemia is important, in order to understand the burden of the disease and its treatment, and to develop improved outcome measures. The goal of this project was to identify key hypoglycemia-related concepts among T2D patients using qualitative interviews. **METHODS:** Participants were 19 T2D patients who were prescribed: 1) an oral anti-diabetic (OAD) and had been diagnosed with T2D in the past 3 years (n = 11); 2) a sulphonylurea (SU) or thiazolidinedione (TZD) that caused weight gain, following the failure of an OAD in the last year (n = 5); or 3) an incretin mimetic that caused weight loss, following the failure of an OAD in the last year (n = 3). One-hour in-person interviews were conducted using a semi-structured interview guide. Interviews were coded using ATLAS.ti software and code frequency was used to identify key experiences. **RESULTS:** Patients were 54.4 years of age on average and 63% were female. Tremor, sweating, and dizziness were the most commonly noted symptoms of hypoglycemia; all five of the patients on an SU or TZD reported experiencing tremor. Patients reported concerns about rare, severe events, such as passing out. Patients generally did not report that their lives were substantially impacted by hypoglycemia, but completing compensatory behaviors to prevent hypoglycemia emerged as an important theme (keeping glucotabs in multiple locations, eating large meals). **CONCLUSIONS:** Hypoglycemia has a negative impact on patients with T2D. Many report experiencing hypoglycemia symptoms, and, although T2D patients do not often report anxiety about hypoglycemia, several reported concerns about the consequences of severe events. Patients also engage in compensatory behaviors, which suggests that avoiding hypoglycemia is important. Further refinement of the concepts associated with the patient's experience of hypoglycemia may yield new PRO instruments that can be implemented in clinical trials with T2D patients.

PDB75

THE IMPACT OF PERCEPTIONS OF WEIGHT ON OVERALL HEALTH-RELATED WELL-BEING IN EUROPEAN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: Maintaining a healthy weight is important in the management of T2DM. We investigated the relationship between weight and patient concerns in relation to overall health-related well-being and function among those with T2DM.